REMARKS

Applicant's attorney thanks the Examiner for reproducing the guideline for section headings. However, the text of the application is not separately segmented in such sections and it is respectfully submitted that the specification reads clearly and smoothly without such headings. Accordingly applicants have chosen to proceed without the optional headings in the specification.

Claims 1-5 and 14-17 were rejected under 35 U.S.C. §102(e) as being anticipated by US Pat. 6,996,430 (Gilboa et al.) Claims 1 describes a method of observing the operation of an invasive medical device comprising operating an invasive medical device from an invasive medical device system to perform an activity within a body; operating an ultrasonic diagnostic imaging system to observe the invasive medical device by means of a real time three dimensional ultrasonic image; producing information with the invasive medical device system having coordinate information relating to the activity; and merging information from the invasive medical device system into the real time three dimensional ultrasonic image at a location in the ultrasonic image data which is determined from the coordinate information. Unlike 3D guided image systems of the prior art, the inventive method avoids the complexity of fusing images from imaging systems of different modalities, resulting in the ability to do 3D image-guided procedures without multiple imaging systems and the attendant complexity. The method of the claimed invention allows a physician to guide an invasive procedure with real time 3D images so that the invasive device is seen in the anatomy in which it is currently operating and not in a previously acquired image set or model image. This is critical for many procedures where the invasive device must proceed through a tortuous path in the body and not simply in a straight line which would be accommodated by a 2D image, and where the anatomy moves as the procedure progresses, where previously acquired images fail to capture the true current position of organs and vessels in the body.

Gilboa et al. describes a medical image guidance system which produces projection images of the body during interventional guidance. This is unlike the claimed invention which produces real time three-dimensional ultrasound images of an invasive procedure. Projection images are inferior to three dimensional images because, as stated by Gilboa et al. in column 10, lines 4-7, "Depending on the mutual direction between PLOS (preferred line-of-sight) and orientation of the transducer, part and sometimes all, of the information in the ultrasound image may be lost in projection." Gilboa et al. give an example of why this is in column 9, lines 45-63. Suppose the invasive device was a tube which is a half-inch in

diameter and two inches long. A projection image is formed by effectively collapsing all of the planes of an imaged volume in a given line-of-sight onto a single projection plane and displaying that single planar image. If a projection image was formed in the axial direction of the tube, the tube would appear as a circle which is a half inch in diameter in a first planar image on display 160. A clinician observing this image would not know whether this circle was the projection of a sphere, a disc, or a tube. To try to overcome this ambiguity, Gilboa et al. also produce a second projection image from a perpendicular line-of-sight as they state in column 10, lines 7-13, which is shown in a second planar projection image on a second display 162. A perpendicular projection image of the tube of our example would be projected orthogonal to the axis of the tube, and would appear as a rectangle which is two inches long and a half inch wide. A clinician observing this second projection image alone would not know whether it is a projection of a rectangular block, a flat rectangle, or a tube. But if the clinician can view the circle and the rectangle in both projection images at the same time, it is hoped that the clinician will deduce from both shapes that the projected object is a tube. After the projection images have been produced, the coordinates of the invasive probe 170 are added as a graphic symbol on each projection image 160 and 162 as stated in column 10, lines 14-17. This is the principle of the Gilboa et al. system.

Since the clinician is put to the task of trying to discern the orientation of the probe from the two planar projection images, which is not always easy, Gilboa et al. add a further imaging aid, which is a fluoroscopic image 192 from fluoroscope 110 which is shown on another monitor 150. While this additional fluoro image may help in interpreting the two projection images, it also adds further complexity to the system and the requirement that the coordinates of the fluoroscope image (from sensor 134) be calibrated to the coordinates of the probe 170 (sensor 138) and the imaging transducer 120 (sensor 132). The present invention obviates the need for this further complexity as well as the ambiguity of the projection images of Gilboa et al. by displaying an invasive object in a three-dimensional ultrasound image which follows the invasive object in real time. The real time three-dimensional ultrasound image can be turned and rotated by means of the display technique known as dynamic parallax viewing, allowing the clinician to see the invasive object in 3D prospective and to examine the invasive object from different perspectives by varying the dynamic parallax view. Since Gilboa et al. do not produce a real time three dimensional ultrasonic image into which information from the invasive medical device has been merged, it is respectfully submitted that Gilboa et al. cannot anticipate Claim 1 or its dependent Claims 2-8, 10, and 18-19.

In Claim 14, coordinate information from an invasive medical device is produced and is used to produce a real time three dimensional ultrasonic image with spatially coordinated information about the activity of the invasive medical device. A real time three dimensional ultrasonic image is displayed with spatially coordinated invasive medical device activity shown in the three dimensional image. A viewer can thus see in perspective the activity of the invasive device in three dimensions and in real time. Contrary to this, Gilboa et al. only show two planar projection images of an imaging field to which a device graphic symbol is added, which are augmented for assistance in interpretation by a further separate fluoroscopic image. The claimed invention avoids the complexity of such a multi-modality imaging arrangement, avoids the need to coordinate the locational data from both imaging modalities as well as the invasive device, and avoids the ambiguity of trying to discern what the invasive device is doing from two planar projection images. For all of these reasons it is respectfully submitted that Gilboa et al. cannot anticipate Claim 14.

In Claim 15, a 3D image processor is coupled to an ultrasound system with a volumetrically steered ultrasound probe and to an interventional device subsystem so as to produce 3D ultrasound images in real time which contain locational information of an interventional device. Gilboa et al. takes the different approach of using planar projection images of an imaging field, augmented by a separate fluoroscopic image of the image field. The invention of Claim 15 avoids the need for two different imaging modalities as Gilboa et al. use, avoids the need to coordinate the locational data from both imaging modalities as well as the invasive device, and avoids the ambiguity of trying to discern what the invasive device is doing from two planar projection images to which a graphic symbol of an invasive device has been added. For all of these reasons it is respectfully submitted that Gilboa et al. cannot anticipate Claim 15 or its dependent Claims 16-17.

Claims 10-18 and 19 were rejected under 35 U.S.C. §103(a) as being unpatentable over Gilboa et al. in view of US patent appl. pub. 2002/0049375 (Strommer et al.) The Examiner states in this Office action that Strommer et al. discloses displaying a real time ultrasonic image containing merged information from an invasive medical device. But as explained in the previous Amendment in this case, which the Examiner says was persuasive, Strommer et al. do not use real time images. Instead, they use what they call "pseudo-video three-dimensional images" (paragraph [0041]). How they do this is best illustrated by Fig. 6 of Strommer et al. and its explanatory text. They first acquire many 2D images of the image field, noting the phases of the ECG heart signal at which they are acquired. They then strip out any parts of these images which show the surgical tool (step 240). They then

assemble these 2D images into a series of 3D images for the different phases of a heart cycle, which are stored. They then conduct their procedure and receive a live ECG signal (step 230) and location data from the surgical tool (step 238). They use the live ECG signal to determine the current phase of the heart cycle, then use this information to select the 3D image previously stored and formed for that particular phase of the heart (step 244). They then superimpose the surgical tool over the selected, previously stored 3D image (step 246) and display the image (step 248). Since the location of the surgical tool in the image at the time the image was acquired has been stripped out, the only representation of the tool in the image is that of its current location. Strommer et al. must strip out the surgical tool from the earlier-acquired image or else the image would ambiguously show two surgical tools, one where the tool was at the time of image acquisition and another inserted from the current location information. This same sequence of 3D images is used over and over again, with updating of the current position of the surgical tool. Thus, the 3D images are not real time images, they are previously acquired and stored images which are used over and over again to put the current location of the surgical tool into anatomical context.

The fallacy of this approach, of course, is that the clinician is not seeing the organs and tissue of the body as they are during the procedure, but is seeing a set of images which shows where the tissue and organs were in the past. It is inconceivable that a physician would conduct a surgical procedure by use of these deceptive old images. If the physician cut or ablated the wrong tissue, he would never know so because the images would not show the damage. They would only continue to show the tissue as it was prior to the procedure. Regardless of its acceptability, Strommer et al. have the same deficiency as Gilboa et al. Both patents fail to show the display of a real time three dimensional ultrasonic image into which information from an invasive medical device has been merged. Accordingly it is respectfully submitted that Claims 10, 18, and 19, all of which depend from Claim 1, are patentable over Gilboa et al. and Strommer et al.

Claim 1 was provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claim 1 of related, concurrently filed application serial number 10/550,212. However, this '212 application was allowed to become abandoned in favor of this application, and became finally abandoned on August 18, 2009 when the statutory period for responding to the last Office action in that case expired. Accordingly it is respectfully submitted that this provisional rejection is now moot.

Claims 6-9 and 11-13 were said to be allowable if rewritten in independent form. Accordingly Claims 6 and 11 have been rewritten in independent form. Claims 7-9 and 12-

13 depend from the rewritten claims and are now allowable by reason of this dependency. It is respectfully submitted that Claims 6-9 and 11-13 are now allowable.

The prior art newly made of record and not relied upon has been reviewed and is not considered to affect the patentability of the claims as amended and presented above. As an update to applicants' previous citation of a published application of Hunter et al, it is noted that this application issued earlier this month as US Pat. 7,599,730. Hunter et al. is similar to Strommer et al. in that Hunter et al. uses pre-acquired data for a 3D heart model or atlas model, then superimposes the current location of a catheter on a selected one of the previously acquired images for display. See column 12 at lines 38-46.

In view of the foregoing amendments and remarks, it is respectfully submitted that Claims 1-5 and 14-17 are not anticipated by Gilboa et al., that Claims 10, 18 and 19 are patentable over Gilboa et al. and Strommer et al. that there is no longer a double patenting issue, and that Claims 6-9 and 11-13 are now in allowable form. Accordingly it is respectfully requested that the rejection of Claims 1-5 and 14-17 under 35 U.S.C. §102(e), of Claims 10, 18 and 19 under 35 U.S.C. §103(a) be withdrawn, and that Claims 6-9 and 11-13 also be passed on to issuance.

In light of the foregoing amendment and remarks, it is respectfully submitted that this application is now in condition for allowance. Favorable reconsideration is respectfully requested.

Respectfully submitted,

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